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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,693	09/14/2000	Sathasivan Indiran Pather	CIMA 3.0-030 CONT II	2096
530 7590 12/29/2004 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER LAMM, MARINA	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/661,693

## Applicant(s)

PATHER ET AL.

## Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22,23,25-36,83-91 and 93-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22, 23, 25-36, 83-91 and 93-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/1/04 has been entered.
2. Claims pending are 22, 23, 25-36, 83-91 and 93-97. Claims 22, 30 and 97 have been amended.

### ***Double Patenting***

1. The provisional rejection of Claim 95 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-4 of copending Application No. 10/080,016 is maintained for the reasons of the record.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of Claims 22, 23, 25-36, 83-91, 93, 94, 96 and 97 under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (US 6,071,539) is maintained for the reasons of the record.

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4. The rejection of Claim 95 under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. in view of Norling et al. (US 5,958,458) is maintained for the reasons of the record.

***Response to Arguments***

5. Applicant's arguments filed 11/1/04 have been fully considered but they are not persuasive.

The Applicant argues:

"The examiner will appreciate that there is simply no disclosure, recognition or understanding in Robinson of administering an active ingredient across an oral mucosa, of buccal administration, of sublingual administration, or of gingival administration. Nor is there any teaching, suggestion or motivation for adjusting an ingredient or parameter, such as the amount of an effervescent couple and/or pH, in order to improve penetration of an active pharmaceutical agent across the oral mucosa." See p. 9 of the Remarks.

In response, Robinson explicitly teaches that "once the tablet is placed in the patient's mouth, it will disintegrate substantially completely" upon exposure to saliva. See col. 7, lines 50-59; col. 8, lines 7-9. The active ingredients released from the tablet will be inherently absorbed in the mouth (at least to some extent) through the oral mucosa because they are the same active ingredients as claimed in the instant claims, e.g. prochlorperazine. Further, Robinson teaches amount of the effervescent granules in the tablets ranging from about 2 to about 90% by weight of the final tablet composition (see col. 8, lines 26-34), which overlaps with the instantly claimed range of 5 to 80% by weight. Furthermore, the intended use of the claimed tablet (i.e. "for oral administration across the oral mucosa") does not patentably distinguish the claimed tablet from that of

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Robinson. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the Robinson's tablet contains the same ingredients as claimed herein and "substantially completely" disintegrates in the mouth, thus releasing the medicament into the oral cavity, where some of the medicament will be inherently absorbed across the oral mucosa.

Further, the Applicant argues:

"If any transfer across oral mucosa occurs in Robinson, it is a transient, undefined, unintended effect and whether not any occurs has been proposed by examiner, not by reference. Furthermore, is respectfully suggested that such effects have been proposed by the examiner only in view of applicants' teachings and arguments." "The examiner has stated that an active ingredient Robinson will be inherently absorbed in the mouth "at least to some extent." (Final rejection, page 3, lines emphasis supplied). There is no objective evidence of record to sustain this point. Moreover, it is contrary to the overall teaching of Robinson and Robinson's teachings that relevant. Moreover, "[t]he mere fact that certain thing result from a given set of circumstances is not sufficient [to establish inherency.]", *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). A retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. See *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989). It will be appreciated that inherency is predicated on the fact that something will necessary and always happen while obviousness assumes that the claimed invention has not been achieved. Understandably, the Patent Office has a difficult time meeting its burden under these circumstances." See p. 10 of the Remarks.

In response, the transfer of the drug across oral mucosa occurs in Robinson is inherent because the prior art's tablets contain the same ingredients (i.e. effervescent agents and a drug) and "substantially completely" disintegrate in the mouth. In response to applicant's argument that the examiner's conclusion of obviousness is

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based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to the Applicant's argument that "[s]ince the Robinson tablet is directed to administration of a drug by swallowing the disintegrated, dissolved tablet, it is not "suitable for" administration of a medicament across the oral mucosa" (see p. 12 of the Remarks), it is noted that the Applicant's tablet also disintegrates in the mouth and is ultimately swallowed. The only difference between the claimed tablet and the Robinson's tablet seems to be in the method of using the tablet. Thus, the claimed tablet is kept in the mouth for a certain period of time, while the Robinson's tablet is swallowed right after it disintegrates. However, such difference is not recited in the instant claims.

### ***Conclusion***

6. No claim is allowed at this time.
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,117,912; US 2001/0006677.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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12/23/04

